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## **DEPARTMENT OF HOMELAND SECURITY**

### **U.S. Customs and Border Protection**

#### **Modification of National Customs Automation Program (NCAP) Test Concerning the Submission of Certain Data Required by the Food and Drug Administration (FDA) Using the Partner Government Agency (PGA) Message Set through the Automated Commercial Environment (ACE)**

**AGENCY:** U.S. Customs and Border Protection, Department of Homeland Security.

**ACTION:** General notice.

**SUMMARY:** This document announces U.S. Customs and Border Protection's (CBP's) plan to conduct a National Customs Automation Program (NCAP) test concerning the electronic transmission of certain import data for all Food and Drug Administration (FDA)-regulated commodities. Under the pilot, this data will be transmitted electronically through the Automated Broker Interface (ABI) for processing in CBP's Automated Commercial Environment (ACE) system utilizing the Partnering Government Agency (PGA) Message Set.

**DATES:** The FDA PGA Message Set test will begin no earlier than [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. This test will continue until concluded by way of announcement in the **Federal Register**. Public comments are invited and will be accepted through the duration of the test pilot.

**ADDRESSES:** Comments concerning this notice and any aspect of this test may be submitted at any time during the test via email to Josephine Baiamonte, ACE Business Office (ABO), Office of International Trade, at [josephine.baiamonte@cbp.dhs.gov](mailto:josephine.baiamonte@cbp.dhs.gov). In the subject line of your email, please indicate, “Comment on FDA PGA Message Set Test FRN”.

**FOR FUTHER INFORMATION CONTACT:** For PGA-related questions, contact Elizabeth McQueen at [elizabeth.mcqueen@cbp.dhs.gov](mailto:elizabeth.mcqueen@cbp.dhs.gov). For technical questions related to the Automated Commercial Environment (ACE) or Automated Broker Interface (ABI) transmissions, contact your assigned client representative. Interested parties without an assigned client representative should direct their questions to Steven Zaccaro at [steven.j.zaccaro@cbp.dhs.gov](mailto:steven.j.zaccaro@cbp.dhs.gov) with the subject heading “PGA Message Set FDA Test FRN-Request to Participate.” For FDA-related questions, contact Sandra Abbott at [sandra.abbott@fda.hhs.gov](mailto:sandra.abbott@fda.hhs.gov) or Max Castillo at [max.castillo@fda.hhs.gov](mailto:max.castillo@fda.hhs.gov).

Any party seeking to participate in this test must provide CBP, in its request to participate, its filer code and the port(s) at which it is interested in filing the appropriate PGA Message Set information. At this time, PGA Message Set data may be submitted only for entries filed at certain ports. A current listing of those ports may be found at the following link: <http://www.cbp.gov/document/guidance/list-aceitds-pga-message-set-pilot-ports>.

## **SUPPLEMENTARY INFORMATION:**

### **I. Background**

The National Customs Automation Program (NCAP) was established in Subtitle B of Title VI—Customs Modernization (Customs Modernization Act), in the North American Free Trade Agreement Implementation Act, Pub. L. 103-182, 107 Stat. 2057 (19 U.S.C. 1411). Through NCAP, the initial thrust of customs modernization was on trade compliance and the

development of the Automated Commercial Environment (ACE), the planned successor to the Automated Commercial System (ACS). ACE is an automated and electronic system for processing commercial trade data which is intended to streamline business processes, facilitate growth in trade, ensure cargo security, and foster participation in global commerce, while ensuring compliance with U.S. laws and regulations and reducing costs for U.S. Customs and Border Protection (CBP) and all of its communities of interest. The ability to meet these objectives depends on successfully modernizing CBP's business functions and the information technology that supports those functions. The Automated Broker Interface (ABI) is the electronic data interchange (EDI) that enables members of the trade community to file electronically required import data with CBP and transfers that data to ACE.

CBP's modernization efforts are accomplished through phased releases of ACE component functionality designed to replace specific legacy ACS functions. Each release will begin with a test and will end with mandatory use of the new ACE feature, thus retiring the legacy ACS function. Each release builds on previous releases and sets the foundation for subsequent releases.

For the convenience of the public, a chronological listing of **Federal Register** publications detailing ACE test developments is set forth below in Section XV, entitled, "Development of ACE Prototypes." The procedures and criteria related to participation in the prior ACE test pilots remain in effect unless otherwise explicitly changed by this or subsequent notices published in the **Federal Register**.

## **II. Authorization for the Test**

The Customs Modernization Act provisions provide the Commissioner of CBP with authority to conduct limited test programs or procedures designed to evaluate planned

components of the NCAP. The test described in this notice is authorized pursuant to §101.9(b) of title 19 of the Code of Federal Regulations (19 CFR 101.9(b)) which provides for the testing of NCAP programs or procedures. See Treasury Decision (T.D.) 95-21.

### **III. International Trade Data System (ITDS)**

This test is also in furtherance of the International Trade Data System (ITDS) key initiatives, set forth in section 405 of the Security and Accountability for Every Port Act of 2006 (“SAFE Port Act”), Sec. 405, Pub. L. 109-347, 120 Stat. 1884 (19 U.S.C. 1411(d)) and in Executive Order 13659 of February 19, 2014, Streamlining the Export/Import Process for America’s Businesses, 79 FR 10657 (February 25, 2014). The purpose of ITDS, as stated in section 405 of the SAFE Port Act, is to eliminate redundant information requirements, efficiently regulate the flow of commerce, and effectively enforce laws and regulations relating to international trade, by establishing a single portal system, operated by CBP, for the collection and distribution of standard electronic import and export data required by all participating Federal agencies. CBP is developing ACE as the “single window” for the trade community to comply with the ITDS requirement established by the SAFE Port Act.

Executive Order 13659 requires that by December 31, 2016, ACE, as the ITDS single window, have the operational capabilities to serve as the primary means of receiving from users the standard set of data and other relevant documentation (exclusive of applications for permits, licenses, or certifications) required for the release of imported cargo and clearance of cargo for export, and to transition from paper-based requirements and procedures to faster and more cost-effective electronic submissions to, and communications with, U.S. government agencies.

### **IV. Partner Government Agency (PGA) Message Set**

The PGA Message Set is the data needed to satisfy the PGA reporting requirements. ACE enables the message set by acting as the “single window” for the submission of trade-related data required by the PGAs only once to CBP. Once validated, the data will be made available to the relevant PGAs involved in import, export, and transportation-related decision making. The data will be used to fulfill merchandise entry requirements and may allow for earlier release decisions and more certainty for the importer in determining the logistics of cargo delivery. Also, by virtue of being electronic, the PGA Message Set will eliminate the necessity for the submission and subsequent handling of paper documents.

At this time, a limited number of ports of entry will be accepting FDA PGA Message Set data. A list of those ports is provided at the following link:

<http://www.cbp.gov/document/guidance/list-aceitds-pga-message-set-pilot-ports>. CBP may expand the list of ports accepting FDA PGA Message Set data in the future. Any expansion to include additional ports will be published on the aforementioned link.

## **V. The Food and Drug Administration PGA Message Set Test**

Section 801 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381) authorizes the Secretary of Health and Human Services (HHS), through the FDA, to make admissibility decisions for FDA-regulated commodities (foods, drugs, cosmetics, medical devices, and tobacco products), and prior notice risk and threat assessment decisions for imported food products. Moreover, section 536 of the FD&C Act (21 U.S.C. 360mm) and 42 U.S.C. 264 provide similar authority for radiation emitting products and human cell, tissue, and cellular and tissue-based products (HCT/Ps). Carrying out these responsibilities involves close coordination and cooperation between the FDA and CBP.

Until October 1998, importers were required to file manual entries on Office of Management and Budget (OMB)-approved forms which were accompanied by related documents. Thereafter, the FDA implemented an automated nationwide entry processing system known as the “Operational and Administrative System for Import Support (OASIS)” that enabled the FDA to more efficiently obtain and process the information it requires to fulfill its regulatory responsibilities. Most of the data that the FDA requires to make admissibility and prior notice-related decisions regarding imported products is already provided electronically by importers and entry filers to CBP. Since CBP relays the entry data to the FDA using an electronic interface as discussed below, most of the data submitted by an importer or entry filer need be completed only once.

Information for commercial entries for shipments of FDA-regulated products that are imported or offered for import into the United States is submitted by the importer (or his or her agent) or entry filer through CBP’s Automated Broker Interface of the Automated Commercial System (ABI/ACS) into OASIS. For imported foods and feeds, this process includes the submission of prior notice information, which is reviewed for targeting higher-risk shipments for examination by the FDA or CBP upon arrival at the port of entry. With respect to the transmission of entry information, the FDA reviews relevant data as part of its admissibility review. The FDA sends a message back to the importer or entry filer with its decision as to whether (1) the product is admissible; (2) additional information is required; (3) an examination of the shipment is required; or (4) the shipment is subject to refusal of admission.

In December of 2011, the FDA fully implemented its new admissibility targeting application called “Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting,” commonly known as “PREDICT.” PREDICT screens all entries, identifies

shipments based on risk, and facilitates FDA's ability to determine whether products should be examined or allowed into the commerce of the United States. After this screening is completed, if PREDICT recommends the product be admitted into the United States, real time notification is provided to the importer or entry filer through OASIS.

In addition to the entry information collected by CBP, the FDA uses additional data elements in order to make an admissibility decision. This information includes the following data elements:

- (1) FDA product code;
- (2) FDA country of production;
- (3) FDA-required information on the manufacturer and shipper; and
- (4) Ultimate consignee.

Additionally, the FDA has identified data elements or Affirmation of Compliance ("A of C") codes that an importer or entry filer may submit upon entry to help expedite the review process. For example, providing the registration number of the manufacture as an A of C may result in an immediate release of the product. Alternatively, an entry filed without the A of C code would be flagged for review and release may be delayed.

If the FDA did not collect this data the agency could not adequately meet its statutory responsibilities to regulate imported products, nor control potentially dangerous products from entering the U.S. marketplace.

This document announces CBP's plan to conduct a new test pilot concerning the submission of electronic FDA data elements required by the FDA's cargo admissibility process under the auspices of ACE for those commodities regulated by the FDA that are being imported or offered for import into the United States. This new FDA PGA Message Set capability will

satisfy the FDA data requirements for formal and informal consumption entries through electronic filing in ACE and via the FDA PGA Message Set. This will enable the trade community to have a CBP-managed “single window” for the submission of data required by the FDA during the cargo importation and review process. For FDA-regulated food products requiring prior notice, the necessary PGA data elements must be submitted prior to the time of arrival of the merchandise. The technical requirements for submitting FDA data elements are set forth in the supplemental Customs and Trade Automated Interface Requirements (CATAIR) guidelines for the FDA. These technical requirements, including the ACE CATAIR chapters, can be found at the following link: <http://www.cbp.gov/trade/ace/catair#field-content-tab-group-tab-4>.

Upon successful completion of the FDA PGA Message Set test, it is anticipated that CBP will decommission the legacy ACS/OASIS interface for the new ACE/OASIS interface.

## **VI. Test Participant Responsibilities**

PGA Message Set test participants will be required to:

- (1) Transmit the appropriate ACE PGA Message Set data, including the additional data elements listed in Section V of this notice, for the commodities and the ports of entry based upon the implementation schedule found at the following link:  
<http://www.cbp.gov/document/guidance/list-aceitds-pga-message-set-pilot-ports>;
- (2) Transmit the PGA Message Set electronically to ACE using ACE Entry or ACE Entry Summary at any time prior to the arrival of the merchandise on the conveyance transporting the cargo to the United States;
- (3) Transmit PGA Message Set import filings only as part of an ACE Entry or ACE Entry Summary certified for cargo release;



- (4) Transmit import entry filings to CBP via ABI in response to a request for documentation or in response to a request for release information for certified ACE Entry Summaries;
- (5) Only transmit to CBP information that has been requested by either CBP or the FDA;
- (6) Use a software program that has completed ACE certification testing for the PGA Message Set; and
- (7) Take part in a CBP-FDA evaluation of this test.

## **VII. Waiver of Regulation under the Test**

For purposes of this test, those provisions of 19 CFR part 12 that are inconsistent with the terms of this test are waived for test participants only. See 19 CFR 101.9(b). This document does not waive any recordkeeping requirements found in part 163 of title 19 of the Code of Federal Regulations (19 CFR part 163) and the Appendix to part 163 (commonly known as the “(a)(1)(A) list”).

## **VIII. Test Participation and Selection Criteria**

To be eligible to apply for this test, the applicant must:

- (1) Be a self-filing importer who has the ability to file ACE Entry Summaries certified for cargo release or a broker who has the ability to file ACE Entry Summaries certified for cargo release; and
- (2) File prior notices or entries for FDA-regulated commodities.

Test participants must meet all the eligibility criteria described in this document in order to participate in the test program.

## **IX. Application Process**

Any party seeking to participate in the FDA PGA Message Set test should email their CBP Client Representative, ACE Business Office (ABO), Office of International Trade.

Interested parties without an assigned client representative should submit an email message to Steven Zaccaro at [steven.j.zaccaro@cbp.dhs.gov](mailto:steven.j.zaccaro@cbp.dhs.gov) with the subject heading “PGA Message Set FDA Test FRN-Request to Participate”. All email communications should include the subject heading, “Request to Participate in the FDA PGA Message Test.”

Email messages sent to the CBP client representative or Steven Zaccaro must include the applicant’s filer code and the port(s) at which it is interested in filing the appropriate PGA Message Set information. Client representatives will work with test participants to provide information regarding the transmission of this data.

CBP will begin to accept applications upon the date of publication of this notice and will continue to accept applications throughout the duration of the test. CBP will notify the selected applicants by an email message of their selection and the starting date of their participation. Selected participants may have different starting dates. Anyone providing incomplete information, or otherwise not meeting participation requirements, will be notified by an email message and given the opportunity to resubmit its application.

## **X. Test Duration**

The initial phase of the pilot test will begin no earlier than [DATE OF PUBLICATION IN THE FEDERAL REGISTER]. At the conclusion of the test pilot, an evaluation will be conducted to assess the effect that the FDA PGA Message Set has on expediting the submission of FDA importation-related data elements and the processing of FDA entries. The final results of the evaluation will be published in the **Federal Register** and the Customs Bulletin as required by §101.9(b)(2) of the CBP regulations (19 CFR 101.9(b)(2)). Any future expansion in ACE including but not limited to any additional PGA commodities and eligible environments (i.e., truck, ocean, rail, air) will be announced via a separate **Federal Register** notice.

## **XI. Comments**

All interested parties are invited to comment on any aspect of this test at any time. CBP requests comments and feedback on all aspects of this test, including the design, conduct and implementation of the test, in order to determine whether to modify, alter, expand, limit, continue, end, or fully implement this program.

## **XII. Paperwork Reduction Act**

The collection of information contained in this FDA PGA Message Set test has been approved by the Office of Management and Budget (OMB) in accordance with the requirements of the Paperwork Reduction Act (44 U.S.C. 3507) and assigned OMB control number 0910-0046. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by OMB.

## **XIII. Confidentiality**

Data submitted and entered into the ACE Portal includes information that is exempt or restricted from disclosure by law, such as by the Trade Secrets Act (18 U.S.C. 1905). As stated in previous notices, participation in this or any of the previous ACE tests is not confidential and upon a written Freedom of Information Act (FOIA) request, a name(s) of an approved participant(s) will be disclosed by CBP in accordance with 5 U.S.C. 552.

## **XIV. Misconduct under the Test**

A test participant may be subject to civil and criminal penalties, administrative sanctions, liquidated damages, or discontinuance from participation in this test for any of the following:

- (1) Failure to follow the terms and conditions of this test;

- (2) Failure to exercise reasonable care in the execution of participant obligations;
- (3) Failure to abide by applicable laws and regulations that have not been waived; or
- (4) Failure to deposit duties or fees in a timely manner.

If the Director, Business Transformation, ACE Business Office (ABO), Office of International Trade, finds that there is a basis for discontinuance of test participation privileges, the test participant will be provided a written notice proposing the discontinuance with a description of the facts or conduct warranting the action. The test participant will be offered the opportunity to appeal the Director's decision in writing within 10 calendar days of receipt of the written notice. The appeal must be submitted to Acting Executive Director, ABO, Office of International Trade, by emailing [Deborah.Augustin@cbp.dhs.gov](mailto:Deborah.Augustin@cbp.dhs.gov).

The Acting Executive Director will issue a decision in writing on the proposed action within 30 working days after receiving a timely filed appeal from the test participant. If no timely appeal is received, the proposed notice becomes the final decision of the Agency as of the date that the appeal period expires. A proposed discontinuance of a test participant's privileges will not take effect unless the appeal process under this paragraph has been concluded with a written decision adverse to the test participant.

In the case of willfulness or those in which public health, interest, or safety so requires, the Director, Business Transformation, ABO, Office of International Trade, may immediately discontinue the test participant's privileges upon written notice to the test participant. The notice will contain a description of the facts or conduct warranting the immediate action. The test participant will be offered the opportunity to appeal the Director's decision within 10 calendar days of receipt of the written notice providing for immediate discontinuance. The appeal must be submitted to Acting Executive Director, ABO, Office of International Trade, by emailing

[Deborah.Augustin@cbp.dhs.gov](mailto:Deborah.Augustin@cbp.dhs.gov). The immediate discontinuance will remain in effect during the appeal period. The Executive Director will issue a decision in writing on the discontinuance within 15 working days after receiving a timely filed appeal from the test participant. If no timely appeal is received, the notice becomes the final decision of the Agency as of the date that the appeal period expires.

## **XV. Developments of ACE Prototypes**

A chronological listing of **Federal Register** publications detailing ACE test developments is set forth below:

- ACE Portal Accounts and Subsequent Revision Notices: 67 FR 21800 (May 1, 2002); 69 FR 5360 and 69 FR 5362 (February 4, 2004); 69 FR 54302 (September 8, 2004); 70 FR 5199 (February 1, 2005).
- ACE System of Records Notice: 71 FR 3109 (January 19, 2006).
- Terms/Conditions for Access to the ACE Portal and Subsequent Revisions: 72 FR 27632 (May 16, 2007); 73 FR 38464 (July 7, 2008).
- ACE Non-Portal Accounts and Related Notice: 70 FR 61466 (October 24, 2005); 71 FR 15756 (March 29, 2006).
- ACE Entry Summary, Accounts and Revenue (ESAR I) Capabilities: 72 FR 59105 (October 18, 2007).
- ACE Entry Summary, Accounts and Revenue (ESAR II) Capabilities: 73 FR 50337 (August 26, 2008); 74 FR 9826 (March 6, 2009).
- ACE Entry Summary, Accounts and Revenue (ESAR III) Capabilities: 74 FR 69129 (December 30, 2009).

- ACE Entry Summary, Accounts and Revenue (ESAR IV) Capabilities: 76 FR 37136 (June 24, 2011).
- Post-Entry Amendment (PEA) Processing Test: 76 FR 37136 (June 24, 2011).
- ACE Announcement of a New Start Date for the National Customs Automation Program Test of Automated Manifest Capabilities for Ocean and Rail Carriers: 76 FR 42721 (July 19, 2011).
- ACE Simplified Entry: 76 FR 69755 (November 9, 2011).
- National Customs Automation Program (NCAP) Tests Concerning Automated Commercial Environment (ACE) Document Image System (DIS): 77 FR 20835 (April 6, 2012).
- National Customs Automation Program (NCAP) Tests Concerning Automated Commercial Environment (ACE) Simplified Entry: Modification of Participant Selection Criteria and Application Process: 77 FR 48527 (August 14, 2012).
- Modification of NCAP Test Regarding Reconciliation for Filing Certain Post-Importation Preferential Tariff Treatment Claims under Certain FTAs: 78 FR 27984 (May 13, 2013).
- Modification of Two National Customs Automation Program (NCAP) Tests Concerning Automated Commercial Environment (ACE) Document Image System (DIS) and Simplified Entry (SE): 78 FR 44142 (July 23, 2013).
- Modification of Two National Customs Automation Program (NCAP) Tests Concerning Automated Commercial Environment (ACE) Document Image System (DIS) and Simplified Entry (SE); Correction: 78 FR 53466 (August 29, 2013).
- Modification of NCAP Test Concerning Automated Commercial Environment (ACE) Cargo Release (formerly known as Simplified Entry): 78 FR 66039 (November 4, 2013).

- Post-Summary Corrections to Entry Summaries Filed in ACE Pursuant to the ESAR IV Test: Modifications and Clarifications: 78 FR 69434 (November 19, 2013).
- National Customs Automation Program (NCAP) Test Concerning the Submission of Certain Data Required by the Environmental Protection Agency and the Food Safety and Inspection Service Using the Partner Government Agency Message Set Through the Automated Commercial Environment (ACE): 78 FR 75931 (December 13, 2013).
- Modification of National Customs Automation Program (NCAP) Test Concerning Automated Commercial Environment (ACE) Cargo Release for Ocean and Rail Carriers: 79 FR 6210 (February 3, 2014).
- Modification of National Customs Automation Program (NCAP) Test Concerning Automated Commercial Environment (ACE) Cargo Release to Allow Importers and Brokers to Certify From ACE Entry Summary: 79 FR 24744 (May 1, 2014).
- Modification of National Customs Automation Program (NCAP) Test Concerning Automated Commercial Environment (ACE) Cargo Release for Truck Carriers: 79 FR 25142 (May 2, 2014).
- Modification of National Customs Automation Program (NCAP) Test Concerning Automated Commercial Environment (ACE) Document Image System: 79 FR 36083 (June 25, 2014).
- Announcement of eBond Test: 79 FR 70881 (November 28, 2014).
- eBond Test Modifications and Clarifications: Continuous Bond Executed Prior to or Outside the eBond Test May Be Converted to an eBond by the Surety and Principal, Termination of an eBond by Filing Identification Number, and Email Address Correction: 80 FR 899 (January 7, 2015).

- Modification of National Customs Automation Program (NCAP) Test Concerning Automated Commercial Environment (ACE) Document Image System Relating to Animal and Plant Health Inspection Service (APHIS) Document Submissions: 80 FR 5126 (January 30, 2015).
- Modification of National Customs Automation Program (NCAP) Test Concerning the use of Partner Government Agency Message Set through the Automated Commercial Environment (ACE) for the Submission of Certain Data Required by the Environmental Protection Agency (EPA): 80 FR 6098 (February 4, 2015).
- Announcement of Modification of ACE Cargo Release Test to Permit the Combined Filing of Cargo Release and Importer Security Filing (ISF) Data: 80 FR 7487 (February 10, 2015).
- Modification of NCAP Test Concerning ACE Cargo Release for Type 03 Entries and Advanced Capabilities for Truck Carriers: 80 FR 16414 (March 27, 2015).
- Automated Commercial Environment (ACE) Export Manifest for Air Cargo Test: 80 FR 39790 (July 10, 2015).
- National Customs Automation Program (NCAP) Concerning Remote Location Filing Entry Procedures in the Automated Commercial Environment (ACE) and the Use of the Document Image System for the Submission of Invoices and the Use of eBonds for the Transmission of Single Transaction Bonds: 80 FR 40079 (July 13, 2015).

Dated: August 24, 2015

Brenda Smith  
Assistant Commissioner  
Office of International Trade



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